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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,957	01/22/2002	Jun Yuan	99,134-E	6627

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05/11/2005

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EXAMINER

HUANG, EVELYN MEI

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/914,957

Applicant(s)

YUAN ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-6,9-19,32,33,36-39,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,32,33,36-39,43 and 44 is/are rejected.
- 7) ☒ Claim(s) 4-6, 9-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Claims 1, 4, 5-6, 9-19, 32-33, 36-39, 43-44 are pending. Claims 2-3, 7-8, 20-31, 34-35, 40-42, 45 have been canceled according to the amendment filed on 1-10-2005.

#### ***Election/Restrictions***

2. In response to the restriction requirement mailed on May 14, 2004, Applicants elect the claims of Group I, i.e., claims 4-6, 9-19, and 30-39 in part, and elect schizophrenia as the species for the method claims. Claims of Groups II to VII are withdrawn from further consideration as being drawn to the non-elected invention.

#### ***Claim Rejections - 35 USC § 112***

3. The rejection for Claims 1, 13, 30-39 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment obviating the rejection.

#### ***Claim Rejections - 35 USC § 101***

4. The cancellation of Claims 34, 35 has rendered moot the rejection under 35 U.S.C. 101.

#### ***Duplicate Claims***

5. The cancellation of Claim 31 has rendered moot the objection to its being a substantial duplicate of claim 1.

***Claim Rejections - 35 USC § 112***

6. The rejection for claims 33, 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment incorporating the specific diseases into the claims.

***Claim Rejections - 35 USC § 112***

7. The enablement rejection under 35 U.S.C. 112, first paragraph, is maintained for claims 1, 32, 33, 36-39, 43-44 for reasons of record.

Applicants submit that the amendment has overcome the rejection.

On the contrary, the amendment fail to overcome the rejection because the scope of the amended claims is still not commensurate with that of the objective enablement. The specification is only enabling for making and using the compounds the compounds wherein W is phenyl, X is dihydroimidazolyl, or X is C(O)NR<sub>6</sub>R<sub>7</sub> wherein R<sub>6</sub> is alkyl substituted with optionally substituted phenyl, or R<sub>6</sub> and R<sub>7</sub> together form a 6-membered ring fused to a benzene to form a tetrahydroisoquinoline, as exemplified in claims 4-6, 9-19, for treating pain or chronic pulmonary obstructive disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons set forth in the previous office action.

***Claim Rejections - 35 USC § 102***

8. The rejection for Claim 1 under 35 U.S.C. 102(b) as being anticipated by Burckhardt (DE 829894, abstract) is withdrawn in view of the amendment defining the substituents on the alkyl of R<sub>6</sub> to be cycloalkyl, aryl or heteroaryl, thereby setting a demarcation from the prior art compound wherein the alkyl is substituted with a substituted amino.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 32, 33, 36-39, 43, 44 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A description of R6a in the definition of X is not found in the specification, although species falling within the subgenus of R6a is described.

While imidazoline is described in Table 2c, a description of the imidazolidone in the definition of X is not found in the specification.

A description for R6 as recited in the amended claim 1 is not found in the specification. Furthermore, a species having a cycloalkyl fused to pyridine, pyrimidino, pyridazino or pyrazino as R6 is not described in the specification.

The court has held that ‘whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.’ In re Wilder, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984). See MPEP 2163.05.

The rejection is applicable to claims dependent on claim 1.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 32, 33, 36-39, 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, definition of R6, cycloalkyl cannot have just 1 or 2 carbon atoms as recited in 'C1-C6 cycloalkyl'.

The rejection is applicable to claims dependent on claim 1.

### ***Claim Objections***

11. Claims 1, 32, 33, 36-39, 43-44 are objected to because they contain non-elected subject matter. Amending the claims to the elected subject matter would obviate the rejection.

### ***Allowable Subject Matter***

12. Claims 4-6, 9-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Giardina (WO 97/19926, PTO-1449) discloses a quinoline-4-carboxamide compound as NK-2 receptor antagonists. The instant is a naphthridine-4-carboxamide compound with NK-3 receptor antagonizing activity. Motivation to modify Giardina's compound to arrive at the instant is lacking.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

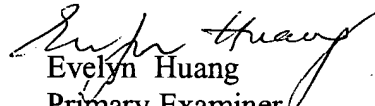
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
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